

JUL 16 2002

K022152  
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## 510(k) Summary

June 30, 2002

**Submitter:** Cambridge Heart, Inc  
1 Oak Park Drive  
Bedford, Ma 01730  
(781) 271-1200  
(781) 275-8431 (Fax)

**Contact:** David Chazanovitz

### 510(k) Numbers and Product Codes of equivalent devices.

Cambridge Heart Heartwave™ Alternans Processing System  
510K Number; #K013564  
Product Code: 74 DPS  
CFR Section: 870.2340

### Indications for Use and Intended Population

The Heartwave™ Alternans Processing System is intended for the measurement of Microvolt T-Wave Alternans\* at rest and during ECG stress testing.

The presence of Microvolt T-wave Alternans as measured by the Analytic Spectral Method of the Heartwave™ Alternans Processing System in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death).

The Heartwave™ Alternans Processing System should be used only as an adjunct to clinical history and the results of other non-invasive and/or invasive tests. The interpretive results of the Alternans Processing System should be reviewed by a qualified physician.

The predictive value of T-wave Alternans for cardiac events has not been established in patients with active, untreated ischemia.

\*Microvolt T-wave Alternans is defined as T-wave alternans which (a) is measured from high-resolution multi-segment sensors, (b) is present in leads X, Y, Z, VM or two adjacent precordial leads, (c) is at the level of 1.9 microvolts after signal optimization and subtraction of the background noise level, (d) is at least three standard deviations greater than the background noise level, (e) has an onset heart rate at or below 110 beats per minute, and (f) is sustained for all heart rates above the onset heart rate.

## Device Description

The Heartwave™ Alternans Processing System is intended for the measurement and recording of T-Wave alternans. The modification which is the subject of this pre-market submission is the modification of a parameter in Alternans Report Classifier software which was cleared for marketing on November 17, 2002 (K03564). Classification software provides the clinician with an indication of positive, negative, or indeterminate result for the Alternans Trend Reports. The results remain subject to the final review of a qualified medical practitioner. The Microvolt T-wave Alternans has been shown to be useful in predicting ventricular tachyarrhythmias and sudden cardiac death.

The Heartwave™ Alternans Processing System provides T-wave alternans diagnostic capabilities to standard stress labs. The Analytic Spectral Method of Alternans Processing used in the Heartwave is intended for the measurement of Microvolt T-wave alternans at rest and during treadmill, ergometer and pharmacologic stress testing. The Alternans Report Classifier provides input to the physician on interpreting the Alternans trend reports.

The alternans test using the Analytic Spectral Method of Alternans Processing is performed with seven standard stress test electrodes and seven proprietary multi-segment Micro-V Alternans™ Sensors. The electrodes and sensors are attached through a leadwire set to the belt-worn patient module, which provides digitized data to the Alternans Processor.

## Standard Hardware Components

<b>Alternans Processor:</b>	Configured for English language and U.S. lead designations
<b>Power Supply:</b>	Modular medical-grade, in-line power supply with universal power input for Alternans Processor
<b>PM-3 w/ Hi-Res™ Leads:</b>	With U.S. lead designations
<b>Printer, w/ data cable:</b>	Inkjet Printer w/data cable & power cord
<b>Line Cords:</b>	IEC 320 line cord with NEMA 5-15P hospital grade plug for Alternans Processor; printer line cord supplied with printer.
<b>Documentation:</b>	Domestic Operator's Manual, Physicians Guide, and TWA Training Program
<b>Shipping Containers:</b>	Mobile pole, Processor unit and Display are shipped in a single container.

## Standard Hardware Accessories

- Patient Cable:** Set of 14 separately detachable lead wires which meet the requirements of 21CFR 898.12 and comply with IEC-601-1; 56.3c part 1.1, General Requirements for Safety
- Individual patient leads are either not detachable, or user detachable with female socket connections such that no conductive surface is exposed when unconnected.
- User Manuals:** Operators manual supplied standard with every system. Training manual supplied in conjunction with training course.
- Patient Electrodes:** Patient electrodes designed and approved specifically for use during exercise stress testing should be used at all times with the Heartwave™ Alternans Processing System.
- Measurement of alternating beat to beat T-wave amplitude (alternans) requires the use of the Cambridge Heart Micro-V Alternans Sensor (Ref: #K002230) in conjunction with other patient electrodes designed and approved specifically for use during exercise stress testing.

## Performance Standards

The Cambridge Heart Heartwave™ Alternans Processing System meets the following Performance Standards:

- ANSI/AAMI EC11-1991
- EN60601-1: 1988, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including Amendments A1 and A2
- EN60601-1-1: 1993, "Medical Electrical Equipment, Part 1: General Requirements for Safety - Section 1.1 Collateral standard: Safety requirements for medical electrical systems"
- EN60601-1-2: 1993, "Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests"
- UL2601-1, "Medical Electrical Equipment, Part 1: General Requirements for Safety" 2<sup>nd</sup> Edition, including Amendments A1 and A2
- CAN/CSA C22.2 No. 601.1-M90, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including C22.2 No. 601.1S1-94 (IEC 601-1, Amendment 1:1991)

## Similarities and Differences to Predicates

The Heartwave™ Alternans Processing System (new) is the same device as in K013564 with the exception of the modification described in this pre-market submission. The Heartwave Alternans Processing System uses the same Analytic Spectral Method as the predicate Heartwave™ for measuring T-Wave Alternans.

## Conclusion

There are more similarities than differences between the predicate device and the Cambridge Heart Heartwave™ Alternans Processing System. Both devices use the Analytic Spectral Method. When used by qualified personnel in accordance with the directions for use, the Heartwave™ Alternans Processing System with Alternans Report Classifier is safe and effective, as indicated, for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUL 16 2002**

Cambridge Heart, Inc.  
c/o Mr. John D. Greenbaum  
Consultant  
Generic Devices Consulting  
20310 SW 48<sup>th</sup> Street  
Ft. Lauderdale, FL 33332

Re: K022152

Trade Name: Heartwave™ Alternans Processing System  
Regulation Number: 21 CFR 870.2340 and 870.1425  
Regulation Name: Electrocardiograph and Programmable Diagnostic Computer  
Regulatory Class: Class II (two)  
Product Code: DPS and DQK  
Dated: June 30, 2002  
Received: July 2, 2002

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna-Bea Tillman".

Donna-Bea Tillman, Ph.D.  
Acting Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number(if known): K022152Device Name: Heartwave™ Alternans Processing System

## Indications For Use:

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PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use     

(Division Sign-Off)

Division of Cardiovascular  
and Respiratory Devices

(Optional Format 1-2-96)

510(k) Number

K022152

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